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EXAMINER

DINGA, ROLAND

ART UNIT

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3766

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,605	Applicant(s) MILLER, SCOTT HUGH	
	Examiner ROLAND DINGA	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) 15-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 42-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>0428/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims **58-62** are objected to because of the following informalities: Claims 58-62 are method claims that are dependent on independent device claim and claims 60-62 are dependent on a non elected claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 58-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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4. Claims 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Kantrowitz et al (US4,630,597).

Regarding claim 1, Kantrowitz discloses an actuator (10) for a heart assist device[see fig.1-3,col.1,lines 9-14], the actuator including: an inflatable balloon (12) having a first body portion (the top portion of the balloon), a second body portion (the bottom portion of the balloon) and a flexure region (36) joining the first and second body portions; and a shroud (14) adjacent the first body portion and having a peripheral extent at least equal to the peripheral extent of the balloon flexure region (36); wherein the balloon (12) and the shroud (14) are shaped such that the shroud (14) restrains a part of the balloon first body portion at or near the flexure region (36) against displacement towards the shroud (14) past a predetermined limit but allows unrestrained displacement away from the shroud (14)[see fig.1-3].

Regarding claim 2, the balloon (12) and the shroud (14) are shaped such that the shroud (12) restrains the part of the balloon (12) first body portion at or near the flexure (36) region against outward displacement during inflation of the balloon (12) but allows unrestrained inward displacement during deflation [see fig.2-3].

Regarding claim 3, during inward displacement, at least part of the inner surface of the balloon (12) second body portion is able to be drawn against at least part of the inner surface of the balloon (12) first body portion [see fig.2-3].

Regarding claim 4, the shroud (14) is generally inwardly concave[see fig.1-3].

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Regarding claim 5, the Shroud (14) is elongated and elliptical [see fig.1-3].

Regarding claim 6, the first body portion, second body portion and flexure region (36) are integrally formed [see fig.2-3].

5. Claims 1 and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Peters et al (US2004/0097784).

Regarding claim 1, Peters discloses an actuator (10) for a heart assist device [see fig.1-3.para.0002, the actuator including: an inflatable balloon (16) having a first body portion (the top portion of the balloon), a second body portion (the bottom portion of the balloon) and a flexure region joining the first and second body portions; and a shroud (12) adjacent the first body portion and having a peripheral extent at least equal to the peripheral extent of the balloon flexure region; wherein the balloon (16) and the shroud (12) are shaped such that the shroud (12) restrains a part of the balloon first body portion at or near the flexure region (36) against displacement towards the shroud (12) past a predetermined limit but allows unrestrained displacement away from the shroud (12) [see fig.1-34.

Regarding 8, a bushing (32) adapted for connection to a motive power source (26) [fig.2-3].

Regarding 9, the balloon (16) also includes a neck portion joined to the first portion, the neck portion being adapted for sealing connection with the bushing (32) [see fig.2-3].

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Regarding claim 10, the shroud (12) also includes a neck portion adapted for sealing connection with the balloon (16) neck portion [see fig.2].

6. Claims 11-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Peters et al (US2004/0097784).

Regarding claim 11, Peters discloses an actuator (10) for a heart assist device[para.0002], the actuator (10) including: a bushing (32) adapted for connection to a pneumatic power source (26)[see fig.3;para.0033]; and an inflatable balloon (16) [para.0006-0007] having a narrower neck portion adapted for sealing connection with the bushing exterior (32)[see fig.2-3], capable of having a wider first and second body portions and an arcuate flexure region joining the first and second body portions, the first body portion having a first end adjacent the neck portion and a second end adjacent the second body portion and being generally inwardly concave, the second body portion being inwardly concave when the balloon (16) is inflated and generally outwardly concave when the balloon (16) is deflated[see fig.1-4].

Regarding claim 12, a shroud (12) having a body portion with a peripheral extent at least equal to the peripheral extent of the balloon first and second body portions [see fig.1].

Regarding claim 13, the balloon (16) and the shroud (12) are shaped such that a part of the balloon first body portion at or near the flexure region is restrained

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against outward displacement past a predetermined limit by the shroud (12) but unrestrained against inward displacement[see fig.1].

Regarding 14, during inward displacement, at least part of the inner surface of the balloon second body portion is able to be drawn directly against at least part of the inner surface of the balloon first body portion[see fig.1-2,4].

7. Claims 42-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Peters (US2004/0097783).

Regarding claim 42, Peters discloses a flexible inflatable balloon (19) for a blood displacing heart assist device (16), the balloon including: a neck portion (20) having first and second ends[see fig.18]; a substantially annular first body portion connected at its inner periphery to the neck (20) portion second end [fig.18]; and a substantially a circular second body portion connected at its outer periphery to the outer periphery of the first body portion, the outer peripheries of the first and second body portions are connected along an annular inwardly concavely curved flexure portion adapted to maintain a radius of curvature during movement of the second body portion between inwardly concave and outwardly concave during deflation and inflation of the balloon (19) respectively [see fig.1,9,10,11,12 and 18].

Regarding claim 43, the balloon (19) is formed as a single piece[see fig.18].

Regarding claim 44, a shroud (17) adapted to overlie and abut the annular first body portion of the balloon 19[see fig.18].

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Regarding claim 45, the shroud (17) is shaped such that the shroud (17) restrains said portion of the balloon at or near the flexure region against outward displacement during inflation of the balloon (19) but allows unrestrained inward displacement during deflation [see fig.18].

Regarding claim 46, the shroud (17) is generally inwardly concave [see fig.18].

Regarding claim 47, the shroud (17) is elongated and elliptical [see fig.18].

Regarding claim 48, the shroud 17 also includes a neck portion (20) adapted for sealing connection with the balloon neck portion [see fig.18].

Regarding claim 49, the shroud (17) is adapted to facilitate bonding of a wrap to the first body portion of the balloon [see fig.18].

8. Claims 42,50-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Peters (US2004/0097784).

Regarding claim 42, Peters discloses a flexible inflatable balloon (19) for a blood displacing heart assist device (16), the balloon including: a neck portion (20) having first and second ends[see fig.18]; a substantially annular first body portion connected at its inner periphery to the neck (20) portion second end [fig.18]; and a substantially a circular second body portion connected at its outer periphery to the outer periphery of the first body portion, the outer peripheries of the first and second body portions are connected along an annular inwardly concavely curved flexure portion adapted to maintain a radius of curvature during movement of the second body portion between inwardly concave and outwardly concave during

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deflation and inflation of the balloon (19) respectively [see fig.1,9,10,11,12 and 18].

Regarding claim 50, a bushing (32) adapted for connection to a pneumatic power source (26)[see fig.2-3].

Regarding claim 51, the bushing (32) is formed with internal restrictions such as secondary lumens to prevent the balloon (16) being sucked into the bushing during deflation of the balloon (16)[see fig.2-3].

Regarding claim 52, the neck portion of the balloon is adapted for sealing connection with the bushing (32)[see fig.2-3].

Regarding claim 53-54, the bushing (32) has a taper adapting the relatively large diameter of the neck of the balloon to the relatively small diameter of a pneumatic fluid line connecting the balloon to a power source (26)[see fig.2-3].

9. Claims 56-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Peters et al (US4, 630,597).Peters discloses an actuator for a heart assist device (16)[see fig.1 and 18], the actuator including: a flexible inflatable balloon (19) having a neck portion (20) connected at one end to a bulbous body portion having a first side and a second side; and a substantially inelastic shroud (17) having a flared portion that extends over the adjacent first side of the balloon bulbous portion, wherein, during deflation, the second side of the bulbous body portion is able to be drawn against the first side of the bulbous body portion [see fig.1 and 18] and the shroud (17) supports the first side of the

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balloon bulbous portion against substantial movement whilst the second side of the balloon bulbous portion is free to move during inflation and deflation [see fig.1 and 18].

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kantrowitz et al (US4,630,597) as applied to claim 6 above, and further in view of Hegde et al (US2004/0147803).

Regarding claim 7, Kantrowitz discloses the invention as claimed but failed to disclose that the flexure region are integrally formed by dip molding. Hegde discloses dip molding [para.0073]. Thus, it would have been obvious to one with ordinary skills in the art to have the flexure region integrally formed by dip molding since dip molding is well known in the art.

Allowable Subject Matter

3. Claim 55 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROLAND DINGA whose telephone number is (571)270-3644. The examiner can normally be reached on Monday through Friday from 8:30am to 5:00pm EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571 272 4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ROLAND DINGA/
Examiner, Art Unit 3766
6/09/2009

/Mark W Bockelman/
Primary Examiner, Art Unit 3766